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2 510(k) Summary

Date Prepared: May 11, 2011

510(k) Number: K111334

Submitter's Name / Contact Person

Manufacturer	**Contact Person**
Vascular Solutions, Inc. 6464 Sycamore Court Minneapolis, MN 55369 USA Tel: 763-656-4300; Fax: 763-656-4250 Establishment Registration # 2134812	Jennifer Ruether Sr. Regulatory Product Specialist

General Information

Trade Name	Benelli Access Device
Common / Usual Name	Catheter, percutaneous
Classification Name	870.1250; DQY; Percutaneous catheter; Class II
Predicate Devices	K021120 Arrow Arterial Catheterization Device (Arrow International, Inc. K032843 Nexiva Closed IV Catheter System (Becton Dickinson Infusion Therapy Systems, Inc.)

Device Description

The Benelli Access Device is a 4 F intravascular over-the-needle catheter consisting of a 6.9 cm high-density polyethylene shaft and a polypropylene hub. The distal end of the shaft terminates in a tapered tip for smooth entry into the vasculature. A polypropylene rotating suture wing is provided on the distal end of the hub and is used to secure the catheter to the patient and prevent dislodgement. The catheter hub has a sidearm that attaches to extension tubing. A three-way stopcock is attached to the distal end of the extension tubing to provide multiple access points to the catheter lumen, allowing for easier flushing, fluid delivery, and blood sampling.

The Benelli Access Device is sold as part of an intravascular catheterization kit. This kit includes the following components:

- Benelli Access Device (4 F x 6.9 cm catheter with sidearm tubing and 3-way stopcock)
- Intraluminal protection system (needleless access port)
- 21 G x 9 cm echogenic needle
- 0.018" x 40 cm guidewire.

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Intended Use / Indications

The Benelli is intended for use in accessing the peripheral vasculature.

Technological Characteristics

The Benelli Access Device is similar to the predicate devices in design and performance. The three devices consist of the over-the-needle catheter design and are available in similar dimensions. The Benelli Access Device and the Nexiva Closed IV Catheter System both have additional access points to allow for device flushing and fluid delivery. The Benelli Access Device utilizes different materials of construction from the predicate devices; however, these materials are commonly used in vascular access devices. Material suitability for the intended clinical use was evaluated through bench testing and biomaterial assessments.

Substantial Equivalence and Summary of Studies

The Benelli Access Device is substantially equivalent to the specified predicate devices based on comparisons of the device functionality, technological characteristics, and Indications for Use. The device design has been qualified through the following tests:

- Insertion force
- Radiopacity
- Liquid leak
- Aspiration
- Tensile
- Corrosion
- Kink

Biocompatibility testing per ISO 10993-1 was performed, consisting of the following tests:

- Cytotoxicity
- Sensitization
- Irritation/intracutaneous reactivity
- Acute systemic toxicity
- Hemocompatibility

Results of the design verification testing and biomaterial assessments did not raise new safety or performance questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Vascular Solutions, Inc.
c/o Ms. Jennifer Ruether
Sr. Regulatory Product Specialist
6464 Sycamore Court
Minneapolis, MN 55369

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Re: K111334
Trade/Device Name: Benelli Access Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: May 11, 2011
Received: May 12, 2011

Dear Ms. Ruether:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111334

Device Name: Benelli Access Device Kit

Indications for Use:

The Benelli is intended for use in accessing the peripheral vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111334

(Posted November 13, 2003)